Remarks

Upon entry of the amendment, claims 1, 13, 17-19, 22, 23, and 24 and new claims 24-74 will be pending. Claims 2-12, 14-16, and 20-21 have been canceled without prejudice or disclaimer. Claims 25-74 have been added. Support for the newly added claims is found throughout the specification as filed. Specifically, support for new claims 25-74 may be found at, for example, Table 1 at page 129, row 6, as indicated as "Gene No. 22;" page 132, line 1 to page 137, line 26; page 138, line 24 to page 147, line 23 (for polypeptide variants); page 149, line 11 to page 152, line 10 (for fragments); page 151, lines 5-22 (for ELISA and Western blot); page 66, line 6 to page 67, line 2 and page 152, line 12 to page 169, line 15 (for antibodies); page 162, lines 3-9; page 182, lines 1-22; page 201, line 25 to page 203, line 4; and page 66, line 6 to page 67, line 2 (for antibody diagnostics); page 207, line 12 to page 209, line 16 and Example 9 (for heterologous); and Examples 5-8 beginning on page 324 (for methods of isolating expressed polypeptide). Thus, no new matter has been introduced.

Applicants note that the present claimed invention is primarily expressed in human ovarian tumor tissue as well as breast and prostate cancer tissue (see page 66, lines 1-2 of the specification). Therefore, the present claimed invention is useful for the diagnosis of cancer (*e.g.*, cancers of the ovaries, prostate and breast). *See* page 66, lines 3-15; and page 66, line 23 to page 67, line 2 of the specification.

In addition, Applicants respectfully assert that the claimed invention fully complies with the requirements of 35 U.S.C. §§ 101 and 102. In particular, Applicants have asserted that the claimed polypeptides are useful, for example, in the diagnosis (*i.e.*, as a diagnostic marker) and/or treatment of specific cancers such as ovarian, prostate and breast cancers. *See, Supra.* These assertions of utility are specific, substantial and credible.

Moreover, Applicants point out that the credibility of the asserted utilities is further supported by data published after the effective filing date of the captioned application for a polypeptide which shares greater than 99% identity to the polypeptide of SEQ ID NO:83. *See*, International Publication No. WO 01/23417, title page, Abstract; and page 55, lines 1-3 (submitted herewith in the Information Disclosure Statement as reference AB). Specifically, the data in reference AB show that this particular protein may be useful in the diagnosis and treatment of cancers (*e.g.*, ovarian and colon). In addition, data from both International Publication Nos. WO 01/60860 and WO 01/51628 (submitted herewith in the Information Disclosure Statement as references AC & AD; see also Geneseq Accession Nos. AAL20351, AAL10187, AAL11452, and AAL19767, also submitted herewith as references AH-AK) further support the asserted utility of the claimed polypeptide HPRBF19. Both international

publications disclose polynucleotides highly expressed in human breast and prostate cancer that share greater than 96% identity to the polynucleotide sequence (SEQ ID NO:32) which encodes SEQ ID NO:83. Therefore, it is clear that independent, third party research entities have confirmed Applicants' credible, specific and substantial asserted utilities.

The Restriction Requirement

The Examiner has required an election under 35 U.S.C. § 121 of one of nine groups cast by the Examiner. The Examiner contends that the individual groupings are distinct, each from each other. *See* page 2 of Paper No. 4.

In order to be fully responsive, Applicants hereby provisionally elect, *with traverse*, Invention Groups XLVIII-XCIV, encompassing newly added claims 25 to 74, drawn to polypeptides of SEQ ID NO:83 and clone ID HPRBF19, for further prosecution (*i.e.*, the polypeptides of Gene 22).

With respect to the Examiner's division of the invention into nine (9) Invention Groups and the reasons stated therefor, Applicants respectfully traverse for the reasons stated below. In the event that the Examiner renders the restriction final, Applicants respectfully reserve the right to petition the restriction requirement under 37 C.F.R. § 1.144.

Applicants submit that, assuming *arguendo*, that two patentably distinct inventions appear in a single application, restriction remains improper *unless* it can be shown that the search and examination of both inventions would entail a "serious burden" (*See* M.P.E.P. § 803). In the present situation, no such showing has been made, particularly with respect to Invention Groups CXLII-CLXXXVIII and CLXXXIX-CCXXXV, wherein the Examiner has assigned the same classification to both, class 514, subclass 2.

Applicants submit that a search of polynucleotide claims of the invention would provide useful information for examining claims directed to both polynucleotides and the polypeptides encoded by these polynucleotides. In certain claims this is especially true because the polynucleotide sequence of these claims is defined in part by the polypeptide that the polynucleotide sequence encodes. Further, Applicants point out that, in many if not most publications, where a published nucleotide sequence is an open reading frame, the authors also include, as a matter of routine, the deduced amino acid sequence of the encoded polypeptide.

Similarly, a search of the polypeptide claims of the invention would clearly provide useful information for the examination of claims directed to antibodies either produced in response to or having affinity for the subject polypeptides. This is because antibodies are

frequently defined by the antigens that they are produced in response to and the epitopes to which they bind. Moreover, in many publications where an antibody is described, the antigen that it was produced in response to is also described.

Further, searches of publications directed to polynucleotides and the use of those polynucleotides would clearly be overlapping. This is so because in many, if not most, publications which describe polynucleotides, these molecules are described by their function, characterization and/or expression profile. Thus, a search of polynucleotide claims would also provide the Examiner with art directed to the manner in which the claimed polynucleotides could be used in diagnostic and therapeutic indications.

Further, searches of publications directed to polypeptides and the use of those polypeptides would clearly be overlapping. This is so because in many, if not most, publications which describe polypeptides, these molecules are described by their function. Thus, a search of polypeptide claims would also provide the Examiner with art directed to the manner in which the claimed polypeptides could be used to treat disease states.

In view of the above, Applicants submit that the searches for polynucleotides, polypeptides, and antibodies; as well as methods of diagnosing, preventing and treating disease states using the nucleic acids and proteins of the subject invention; and methods of identifying an activity in a biological assay of the subject invention; and the translational products produced by the methods of identifying an activity in a biological assay wherein said translational products have said activity would clearly be overlapping. Accordingly, Applicants request that, in view of M.P.E.P. § 803, the claims of all of Invention Groups I to CDXXIII should be searched and examined in the subject application.

Accordingly, Applicants respectfully request that the restriction requirement under 35 U.S.C § 121 be reconsidered and withdrawn and the instant claims be examined in one application.

Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144 should it be made final.

Conclusion

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Date: October 15, 2002

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: **Ruben** *et al.*

Attorney Docket No.: PZ035P1C1

Application Serial No.: 09/895,298

Art Unit: 1646

Filed: July 2, 2001

Examiner: O'Hara, E.

Title: Protein HPRBF19
(as amended)

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Changes to the application follow. Text that has been inserted is underlined and text that has been deleted is struck through.

In the Specification:

The title of the specification has been replaced as follows:

~~**47 Human Secreted Proteins**~~ **Protein HPRBF19**

In the Claims:

Claims 25-74 have been added.